

REMARKS

Although Applicants respectfully disagree with the assertion that any of the subject matter of claims 40-42 is not fully enabled, in an effort to advance prosecution of the instant application, claims 40-42 have been canceled without prejudice or disclaimer. Claim 39 has been amended. Support for the amendment of claim 39 is found, inter alia, in original claim 40. No new matter has been added by any of the amendments. Claims 1-39 and 43-53 remain in the application.

The allowance of claims 1-38 and 43-53 is acknowledged with appreciation.

The rejections of claims 40-42 have been mooted in the instant application by cancellation of the claims. The rejection claim 39 under 35 U.S.C. §112, first paragraph, for alleged lack of enablement is respectfully traversed.

Claim 39 has been amended to specifically direct it to treatment of pain selected from the group consisting of acute pain, chronic pain and neuropathic pain. The Office Action acknowledges that the application is enabling for alleviating acute pain.

With respect to chronic pain, the Examiner's attention is directed to R. Chou et al., "Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain," *The Journal of Pain*, 10(2):113-130 (2009) which is attached as Exhibit 1 to this Reply and which contains a comprehensive review of the extensive literature relating to the use of opioids in the treatment of chronic pain and detailed recommendations of the American Pain Society for the use of opioids to treat chronic pain.

The compounds of the present invention are clearly shown to bind to the ORL-1 receptor and thus are opioids. As such, a person of ordinary skill in the art would be able to use such compounds to treat chronic pain in accordance with

protocols described by Chou et al. and would have a reasonable expectation of success for such treatment.

With regard to neuropathic pain, the Examiner's attention is directed to E. Eisenberg et al., "Opioids for Neuropathic Pain (Review)", *Cochrane Database of Systematic Reviews* 2006, Issue 3, Art. No.: CD006146.DOI: 10.1002/14651858.CD006146, which contains an review of extensive literature dealing with the use of opioids for treating neuropathic pain and which supports the efficacy of opioids in the treatment of neuropathic pain. This conclusion is consistent with that of Ossipov et al., which is already of record, and which likewise concludes that opioids are useful to treat neuropathic pain. Against this background, Applicants respectfully submit that a person of ordinary skill in the art would be able to used the opioids of the present invention to alleviate neuropathic pain in accordance with the detailed protocols reviewed by Eisenberg et al. and additionally described by Ossipov et al., and would have a reasonable expectation of success for such use.

Reconsideration and withdrawal of the lack of enablement rejection of claim 39 are accordingly, respectfully requested.

The Examiner is respectfully requested to confirm her receipt and consideration of the Chou et al. and Eisenberg et al. articles by initialing and returning a copy of the accompanying List of References cited by Applicant.

In view of the foregoing, the application is respectfully requested to be in condition for allowance, and prompt, favorable action thereon is earnestly solicited.


If there are any questions regarding this Reply or the application in general, a telephone call to the undersigned at (202) 624-2845 would be appreciated, since this should expedite the examination of the application.

Application No. 10/758,241
Reply to Office Action
March 13, 2009

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029310.53093US).

Respectfully submitted,

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